MedDRA v5.0 Codes Overview

The Medical Dictionary for Regulatory Activities (MedDRA) v5.0 was implemented by CTEP, replacing MedDRA v1.99, on July 1, 2002. Disease, Therapy, Adverse Event, and Pre-existing Condition data submitted after this date, through the CDUS and AdEERS applications and the Protocol Submission Worksheet were required to use this version of MedDRA. MedDRA v1.99 codes entered on existing protocols were also mapped to MedDRA v5.0.

On October 1, 2003, MedDRA v6.0 replaced v5.0 and all protocols migrated to this new data set. As of October 1, 2004, the CTEP Simplified Disease Classification (CTEP SDC) v1.0 replaced MedDRA v6.0 for submissions that include disease information.

MedDRA v5.0 remains available as reference in the following formats and mapping file:

Text (.txt) file	The text file is a comma delimited file that lists the MedDRA v5.0 codes enclosed within double quotes. It is used for importing the codes into user databases.
Excel (.xls) file	The Excel file lists the MedDRA v5.0 codes.
Mapping Version Excel (.xls) file	The Excel mapping file provides the mapping of MedDRA v1.99 to MedDRA v5.0. All prior data submitted to CTEP based on v1.99, was mapped to v5.0 based on this mapping document.